



Q & A's: Zika Virus Diagnostic Testing

August 11, 2016

This is an evolving situation.

Recommendations will be updated as more information becomes available.

Who should be tested for Zika virus?

Pregnant women who traveled to, or resided in, a Zika-affected area:

- Who had one or more of the following symptoms during or within two weeks of travel: acute onset of fever, rash, arthralgia or conjunctivitis.
- Who traveled within the past 12 weeks and had no symptoms of Zika.
- During the eight weeks before conception can be tested within 12 weeks of that exposure.

Pregnant women who did *not* travel to a Zika-affected area:

- Who had unprotected sexual contact with a partner who traveled to, or resided in, a Zika-affected area.

All others:

- Who traveled to a Zika-affected area and had one or more symptoms of Zika virus infection during or within two weeks of travel.
- Who became symptomatic after unprotected sexual contact with a partner who traveled to a Zika-affected area, where the partner was diagnosed with, or had symptoms of Zika infection.

*Asymptomatic men and non-pregnant women (including those planning pregnancy or undergoing fertility treatment) are not being tested at this time.

What testing is available and where?

PCR:

- Triplex RT-PCR Assay to detect dengue, chikungunya and Zika virus RNA [available at the state health lab].
- Focus Diagnostics Qualitative Real-time RT-PCR and Altona RealStar RT-PCR to detect Zika virus RNA [available through commercial labs].

Serology:

- IgM capture (MAC) ELISA to detect Zika virus IgM [available at the state health lab and through commercial labs].
- Plaque Reduction Neutralization Test (PRNT) to detect total antibody (dengue and Zika virus) [available at CDC; performed on IgM positive or equivocal samples].
- Dengue MAC-ELISA and chikungunya MAC-ELISA [available through commercial labs].

How can patients access Zika virus testing?

Zika virus testing is only available when requested by a health care provider. The state health lab cannot collect samples directly from patients.

What samples should be sent for Zika virus testing?

Serum and urine samples should be submitted for all patients. CSF is also an acceptable sample, but it should be accompanied by serum and urine. Refer to updated CDC guidance for laboratory testing at www.cdc.gov/zika/laboratories/lab-guidance.html

What samples should be collected and how much?

Serum:

- Use a red top, tiger top or serum separator tube.
- The state health lab requires 0.25 mL for RT-PCR testing and ≥ 1.0 mL for MAC-ELISA.
- If requesting both RT-PCR and MAC-ELISA, send ≥ 1.25 mL.

Urine:

- Send the sample in a sterile, screw-capped vial secured with thermoplastic, self-sealing lab film.
- The state health lab requires 0.5 to 1.0 mL for RT-PCR testing.

Cerebrospinal fluid (CSF):

- Send sample in a sterile, screw-capped vial secured with thermoplastic, self-sealing lab film.
- The state health lab requires at least 1.0 mL for RT-PCR or MAC-ELISA.

What is the turnaround time for Zika testing?

- RT-PCR testing at the state health lab will take approximately 72 hours following sample receipt.
- MAC-ELISA at the state health lab will take at least five business days following sample receipt.
- Expect confirmatory PRNT testing at CDC (if IgM is positive or equivocal) to take at least two additional weeks.
- All results will be sent securely to the submitter at the fax number provided on the test request form.

How do I request testing from the lab?

All submitters **MUST** submit the Request for Analytical Services form #270/271. A separate form must be filled out for EACH sample.

- To request the form, call the state health lab (303-692-3485) or state health department (303-692-2700).
- The lab will use the form to set up an account for you if you do not already have one.

All submitters must also complete the CDC 50-34 form.

- The form is available at www.cdc.gov/laboratory/specimen-submission/pdf/form-50-34.pdf, or
- Call 303-692-2700 and we can fax or email the form to you.

The CDC 50-34 form **must be filled out completely** or testing will be delayed.

- Required information for all specimens:
 - Specimen collection date
 - Symptoms
 - Symptom onset date
 - Travel location
 - Travel dates
 - Pregnancy status
 - Suspected exposure route (mosquitoes, sexual transmission, etc.)
- In the 'Test order name' field on page 1 of the form, put **ZIKA**.
- On page 2 under 'Relevant immunization history' indicate if patient has a history of yellow fever or Japanese encephalitis virus vaccination.

What is the cost for testing, and is there a CPT code?

- The RT-PCR test at the state health lab costs \$260 (per sample), billed to the submitter [CPT code 87798].
- The MAC-ELISA test at the state health lab costs \$150 (per sample) [CPT code 86790].
- A \$45 handling and processing fee [CPT code 99001] may apply for certain samples sent to CDC.

How do I get the sample to the state health lab?

- Specimens can be sent to the state health lab by FedEx or by the courier of your choice. The address is CDPHE Laboratory Services Division, 8100 Lowry Blvd, Denver, CO 80230.
 - The state health lab can only accept samples Monday - Friday, 8 a.m. to 5 p.m.
 - FedEx and other couriers should be directed to avoid weekend deliveries.
- Alternately, you may check our current list of pickup times and locations for the state health lab courier,
www.colorado.gov/pacific/sites/default/files/Kangaroo%20Update.7.29.14-SK.pdf
 - If your hospital lab or local health department is on the courier route, you may arrange to have the sample(s) picked up there. Call 303-692-3086 to make arrangements.

Are there special handling and packaging instructions?

Samples should be kept at 4°C and transported on cold packs. The CDPHE courier will transport at 4°C; other overnight shipments should include a cold pack. If the sample is frozen, it should be kept frozen and be shipped on dry ice.

Can samples be submitted to commercial labs for testing?

Under the FDA's Emergency Use Authorization, some commercial labs are performing Zika virus RT-PCR and MAC-ELISA testing. For more information on submitting samples to commercial labs, contact your regular commercial laboratory.

Who can I call for other questions about Zika virus?

Call the state health lab at 303-692-3485 or the state health department at 303-692-2700.

Where can I go for more information on Zika virus?

A list of countries with local transmission of Zika virus is available at www.cdc.gov/zika/geo/active-countries.html

The most up to date testing guidance is available at www.colorado.gov/pacific/cdphe/zika